REPORT DOCUMENTATION PAGE

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1. REPORT DATE *(DD-MM-YYYY)*	2. REPORT TYPE	3. DATES COVERED *(From - To)*
21/03/2017	final	11/02/2013-21/03/2017

4. TITLE AND SUBTITLE
Rapid Extremity Pain Relief by Battlefield Acupuncture after Orthopedic Surgery: A Randomized Clinical Trial.

5a. CONTRACT NUMBER

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Paul Crawford, MD

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Clinical Investigation Program
Mike O'Callaghan Federal Medical Center
4700 Las Vegas Blvd North
Nellis AFB, NV 89191

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
Clinical Investigation Program
Mike O'Callaghan Federal Medical Center
4700 Las Vegas Blvd North
Nellis AFB, NV 89191

10. SPONSOR/MONITOR'S ACRONYM(S)
FDG201234H

11. SPONSOR/MONITOR'S REPORT NUMBER(S)
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12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release; distribution is unlimited.

13. SUPPLEMENTARY NOTES

14. ABSTRACT
See attached

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			Jill Clark
U	U	U	UU		19b. TELEPHONE NUMBER *(Include area code)* (702) 653-3298

APPROVED

MAY 09 2017

60 MDG IRB
TRAVIS AFB CA

DGMC – Human Research
Final Report

1. **DATE:** 27 March 2017

2. **Protocol Number:** FDG20120024H

3. **Title:** Rapid Extremity Pain Relief by Battlefield Acupuncture after Orthopedic Surgery: A Randomized Clinical Trial

4. **Risk:** ☐ **Greater than Minimal Risk** ☒ **Minimal Risk**

5. **Date of Approval:** 11 February 2013

6. **Start Date: 22 May 2013**

7. **Study Staff**

Name	Rank	Study Role	Date of Investigator Training	Staff/ Resident/ Fellow	Dept/ Office Symbol	Phone	DoD Assurance Number	E-mail
Paul Crawford, M.D.	Col	PI	01/12/15	Staff	99MDOS /SGOF	702 653-3298	50417	paul.crawford@us.af.mil
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Eduardo Sevilla, BS	CTR	SC	03/03/16	CTR	60MDOS /SGOF	707 423-7263	50004	eduardo.sevilla2.ctr@mail.mil

8. Study Status:
(Check one only)

☐ Inactive, protocol never initiated
☐ Inactive, protocol initiated but has not/will not be completed
☒ All approved procedures/uses have been completed

9. Number of Subjects Entered into the Study: For multiple sites, add rows to the table below for each site.

	Number approved to enroll	**Number enrolled**	**Withdrawals**
Number of subjects enrolled at DGMC	87	19	2
Number of subjects enrolled at MOFMC	260	260	40

9.1. Summary of Unanticipated Problems and Adverse Events:
The study had Unanticipated Problems:

☒ Yes ☐ No

The study had Adverse Events:

☒ Yes ☐ No

All adverse, serious adverse and unexpected events were reported IAW SGSE 40-402-01:

☒ Yes ☐ No ☐ N/A

List all the local and sponsor reported unanticipated problems, serious and non-serious adverse events, reported to the sponsor and protocol deviations that resulted in subject harm since the last progress report.

Type of Event	**Date of Event**	**Date Reported**	**Nature of Event**	**Site of Event (for multisite)**	**Outcome**
Unanticipated AE	9/15/14	9/18/14	Patient reported acupuncture needle broke off in ear when she rubbed it with a towel-no pain or discomfort reported	Nellis AFB	X-ray exam showed no retained needle. Patient had no pain or discomfort. She stated she thinks the broken piece fell out of ear.

*Unexpected adverse event, severe adverse event, or adverse event

Reminder if these events were study related, caused harm or increased the risks to subjects or others, they should have already been reported when discovered, using the Adverse or Unexpected Adverse Event report form. This is only a summary of those events.

9.2. Summary of Withdrawals from the Study: If none occurred, state NONE. List all subjects who withdrew (please specify if the subject withdrew, is lost to follow-up, deceased or any other reasons from your study)

For the Entire Study Chronologically

Date of Withdrawal	Withdrawals Due to Screening Failure	Participant withdrawal (reason)
5/24/2013		012: Patient unable to be seen within the 30min post-op time frame
6/11/2013		023: Patient deployed, surgery canceled
6/27/2013		019: Patient surgery scheduled to different time. Research assistant missed surgery
6/27/2013		024: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
7/23/2013		DGMC 003: 7/23/13- BFA Participant 5003 was dropped from BFA Study. Reason: BFA 5003's wife had DGMC MD remove the BFA Needles due to concern of her pet cats might eat the BFA needles
8/13/2013		039: No doctor was able to apply BFA/Placebo
8/23/2013		034: 2nd Surgery within 30 days
8/27/2013		048: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
9/5/2013		051: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
9/5/2013		060: Patient called and decided to not participate
9/11/2013		056: Patient was experiencing chest pain following surgery Decision was made to remove her from study
9/12/2013		047: No doctor was able to apply BFA/Placebo
10/20/2013		036: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
11/27/2013		077: Patient ended up having a second surgery within the 1 month of participation
12/18/2013		091: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
1/8/2014		084: Patient did not have a phone and was unable to be reached for the follow up calls
3/17/2014		121: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
3/28/2014		125: Patient had extended hospital stay due to surgery complications
5/1/2014		134: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
5/6/2014		138: Patient returned to hospital for second surgery
6/13/2014		149: No doctor was available to perform the BFA for the study

7/9/2014		155: Patient discharged to rehab facility-unable to contact
7/9/2014		DGMC 001: Research Assistant signed the Inclusion/Exclusion Document on 6/19/13. Associate Investigator was unavailable to sign the Inclusion/Exclusion Document until 6/20/13. The ICD Consent Document was signed by the Associate Investigator a day later than BFA Research Assistant's ICD consenting visit on 6/19/13. BFA 5001 Participant was dropped from the BFA Study Reason: ICD document signature date obtained from Associate Investigator is a day later than Research Assistant consenting signature date of 6/19/13
8/8/2014		164: Patient choose not to participate
8/11/2014		168: No doctor was available to perform the BFA for the study
9/22/2014		175: Patient unable to be reached for follow up
9/26/2014		184: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
10/31/2014		021: Patient opted to not undergo surgery
10/31/2014		190: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
10/31/2014		191: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
11/15/2014		195: Research staff unavailable to perform study related procedures at the time the surgery took place
11/26/2014		197: Research staff unavailable to perform study related procedures at the time the surgery took place
12/16/2014		203: Patient surgery time was changed. Research staff unavailable to perform study related procedures at the time the surgery took place
1/8/2015		205: Research staff unavailable to perform study related procedures at the time the surgery took place
1/13/2015		207: Research staff unavailable to perform study related procedures at the time the surgery took place
2/27/2015		213: No doctor was available to perform the BFA for the study
3/20/2015		223: No doctor was available to perform the BFA for the study
4/14/2015		232: No doctor was available to perform the BFA for the study
5/14/2015		234: Patient surgery was cancelled
5/26/2015		243: Patient choose not to participate
6/15/2015		244: Patient choose not to participate
01/05/16		248: No doctor was available to perform the BFA for the study

9.3. Consent Process:

Each participant was recruited in accordance with the recruitment plan approved by the IRB.

☒ Yes ☐ No

Each participant was consented in accordance with the consent process approved by the IRB.

☒ Yes ☐ No

Each participant was given a copy of the signed, dated informed consent document.

☒ Yes ☐ No

As the PI, I have retained a copy of each participant's signed, dated informed consent document and provided a copy to the Protocol Office for record.

☒ Yes ☐ No

10. Study Deviations

Have any minor non-compliance events occurred? ☐ Yes ☒ No

Have any serious non-compliance events occurred? ☐ Yes ☒ No

I certify that no changes have occurred in the protocol since the previous IRB review. ☒ Yes ☐ No

11. Complaints about the Study:

Have there been any reported complaints regarding the study?

☐ Yes ☒ No

12. Amendments:

For the Entire Study Chronologically

Date of Change	Date of Approval	Summary of the Change
29 Apr 13	29 Apr 13	Amendment 1: Personnel Changes, update study staff phone numbers
9 May 13	10 May 13	Amendment 2: Change the word 'prior' to 'after' in section 6.4.
29 May 13	11 Jun 13	Amendment 3: Removed AI, addition of recruitment flyer
23 Sept 13	24 Sept 13	Amendment 4: Added SC, and add/removed AIs
26 Sept 13	24 Oct 13	Amendment 5: Revised section on page 5 regarding overnight stay
26 Nov 13	2 Jan 14	Amendment 6: Removed/added AI's and SC. Changed commander
20 Mar 14	18 Apr 14	Amendment 7: Revised data collection tool, added exclusion criteria, increased recruitment
15 Jul 14	12 Aug 14	Amendment 8: Removed/added AIs, updated Patient Advocate on ICD and Privacy Officer on HIPAA
22 Sept 14	7 Oct 14	Amendment 9: Updated risks in response to unanticipated event of possible needle breakage
7 Aug 15	Disapproved 10 Jun 2016	Amendment 10: Revised data collection tool, increased recruitment
29 June 16	12 July 16	Amendment 11: Revised data collection tool, add/remove AI's and SC.

13. Funding: Funding from: ☐R&D ☐SGO ☐O&M ☐HMJ ☒OTHER (explain source): We were awarded a grant through Intramural DHP 6.7 FY12 the Funding Opportunity in the amount of $ 249,999 and was approved for additional $130,000 of DHP 6.7FY13 funds.

I have received External Resources to support this study in the form of:
(select all those applicable):

☐ Loaned equipment
☐ Consumable supplies
☐ Drugs from a non-DoD source
☒ N/A

14. Summary of Research Findings:

Background: Due to the emergence of improvised explosive devices (IED's) and the widespread use of body armor, there have been a higher proportion of orthopedic injuries from secondary blast injury than in previous conflicts. Since 2003, it is estimated that approximately 32,195 soldiers have been wounded in combat in the Iraq conflict alone. According to the American Academy of Orthopedic Surgeons, more than four and one half million knee arthroscopies and total knee replacements are performed worldwide each year in addition to millions of foot

and ankle surgeries. These invasive procedures result in swelling and pain. The side effects of the pain medications are well known and a decrease in their use could prevent adverse effects of sedation and decreased job performance. Auricular acupuncture has been evaluated in multiple trials, and although generally proven to be useful, these trials were not rigorous. This study seeks to determine if modified Battlefield Acupuncture is more effective at relieving acute extremity pain, reducing medication use, decreasing time to full ambulation and improving quality of life than placebo acupuncture or standard care after lower extremity surgery.
Methods: We conducted a multi-site 3-arm randomized, double blind controlled trial of standard care alone versus standard care + placebo auricular acupuncture with ASP needles versus standard care + battlefield acupuncture with semi-permanent needles. We recruited subjects at the pre-operative visit within two Air Force orthopedics clinics for lower extremity surgery (knee or below). After consent, we randomized them to the above interventions. After surgery, within 30 minutes of arrival in the post-operative care unit, subjects received their designated intervention. Acupuncture was performed by physician acupuncturists. Subjects reported pain level immediately after acupuncture, 24, 28, 168, and 720 hours later to a blinded research associate. Additionally, subjects completed a PIQ-6 30 days post-operatively, and opioid use was tracked for 30 days post-operatively. Statistical analysis with ANOVA, Pearson's correlation, Chi-square and Fisher's exact test, and multivariate analyses were performed on the data.
Results: We enrolled 233 Department of Defense beneficiaries >18 years old (92 females and 141 males) with a mean age of 44.5 years at two Air Force Medical Centers. We randomized 81 to modified BFA, 74 to placebo acupuncture and 78 to standard care. Overall pain levels were unchanged at each time point between groups. Subjects with worse pain were noted to take more opioid medication, and subjects older than 50 years who received modified BFA took 398 fewer morphine equivalent units than those who received standard therapy (p=.09)
Conclusion: The use of modified battlefield acupuncture protocol does not change pain over 30 days, but both modified BFA and sham acupuncture may reduce use of opioid analgesics in those >50 years of age.

15. Publications and Presentations for this research study: None

16. Defense Technical Information Center (DTIC) Abstract Submission (MANDATORY per AFSG/SG-5)

Objective: This study seeks to determine if modified Battlefield Acupuncture is more effective at relieving acute extremity pain, reducing medication use, decreasing time to full ambulation and improving quality of life than placebo acupuncture or standard care after lower extremity surgery.
Methods: We conducted a multi-site 3-arm randomized, double blind controlled trial of standard care alone versus standard care + placebo auricular acupuncture with ASP needles versus standard care + battlefield acupuncture with semi-permanent needles. We recruited subjects at the pre-operative visit within two Air Force orthopedics clinics for lower extremity surgery (knee or below). After surgery, within 30 minutes of arrival in the post-operative care unit, subjects received their designated intervention. Acupuncture was performed by physician acupuncturists. Subjects reported pain level immediately after acupuncture, 24, 28, 168, and 720 hours later to a blinded research associate. Additionally, subjects completed a PIQ-6 30 days post-operatively, and opioid use was tracked for 30 days post-operatively. Statistical analysis with ANOVA, Pearson's correlation, Chi-square and Fisher's exact test, and multivariate analyses were performed on the data.
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Grant Number: 20122019
From: DHP 6.7

16. Signature of Principal/Associate Investigator:

Paul Crawford, MD, Col
Type/Print Name of Investigator

Signature

4-17-17
Date

CC: None
Attachments: None